



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

EC

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,119	02/26/2002	Arthur D. Gershowitz	032722-593	3521

7590 07/07/2003

Platon N. Mandros, Esq.
BURNS, DOANE, SWECKER & MATHIS, L.L.P.
P.O. Box 1404
Alexandria, VA 22313-1404

[REDACTED] EXAMINER

KONTOS, LINA R

ART UNIT	PAPER NUMBER
	3763

DATE MAILED: 07/07/2003

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/082,119	GERSHOWITZ, ARTHUR D.
	Examiner	Art Unit
	Lina Kontos	3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on amendment filed on June 19, 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.
- 4) Claim(s) 1-8, 15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 15 and 16 is/are allowed.
- 6) Claim(s) 1-8 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 26 February 2002 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 3763

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

*1.
synt'lumen 18*

Claims 1,2,5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Cragg et al.

Cragg et al. teaches a balloon catheter comprising three lumens: one for accommodating a guiding mechanism (column 8, lines 45-46), a proximal lumen for the delivery of an agent to the patient's vasculature, and a third for the inflation of the balloon member (column 9, lines 47-49). Infusion lumen communicates with the interior of balloon sealing member (Figure 3) and exit port, 60, in the wall of the balloon to facilitate the delivery of infusion fluid (column 10, line 23-24).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2.

Claims 3,4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg et al.

Cragg et al. discloses the claimed invention except that the lumens of the catheter are not coaxially oriented. It would have been obvious to one having ordinary skill in the art at the time of the invention was made to have the sylet lumen coaxially formed within the infusion lumen, since it has been held that rearranging parts of an invention involves only routine skill in the art.

In re Japikse, 86 USPQ 70.

3.

Claim 8 rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg in view of O'Neill et al.

Cragg, as described above, teaches a multi-lumen catheter, but fails to teach a pressure-monitoring lumen.

O'Neill et al., as described above, teaches a multi-lumen catheter with an inflatable balloon assembly comprising an infusion, pressure-sensing, and inflation lumens (column 6, lines 37-38).

It would have been obvious to one skilled in the art at the time of the invention to incorporate a pressure-sensing lumen in the catheter device for the purposes of monitoring the pressure in the patient's vasculature.

Response to Arguments

Applicant's arguments filed June 19, 2003 have been fully considered but they are not fully persuasive.

4.

In regards to claim 1, Examiner notes applicant's response that the embodiment of the Cragg et al. patent disclosing a stylet lumen fluidly isolated from the expandable element is a separate embodiment from the stylet lumen having a sealing means at its distal end. However, in response to applicant's argument that the sealing member is disposed on the fluidly isolated stylet lumen for the reason of ensuring inflating fluid is delivered solely to the balloon and does not flow out of the cannula, the fact that applicant uses this feature for a different purpose does not alter the conclusion that its use in a prior art device would be *prima facie* obvious from the purpose disclosed in the reference." *In re Lintner*, 173 USPQ 560. Additionally, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

5.

Applicant's arguments, see pages 7-8, filed June 19, 2003, with respect to claim 15 have been fully considered and are persuasive. The rejections of claims 15,16 have been withdrawn as none of the prior art of record discloses a multilumen catheter with separate stylet and infusion lumens wherein the stylet is first inserted into the catheter, withdrawn, and then the infusion fluid is conducted through a separate adjacent lumen.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

Art Unit: 3763

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lina Kontos whose telephone number is (703) 306-4207. The examiner can normally be reached on M-F 8:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

LRK LRK
July 3, 2003 7-303



MICHAEL J. HAYES
PRIMARY EXAMINER